Certificate of Completion

This is to certify that

Jens Christian Kallesøe True

participated in the course

Software development - regulatory requirements

Organized by Key2compliance AB
September 21-23, 2020

Instructor
Cyrille Michaud

The course content is specified on page 2 of this document.

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Software development - regulatory requirements

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Course content:

Day 1:
• EU Medical Device Regulation
 –Brief on EU regulations, main requirements and consequences for SW dev team
• FDA regulations
 –Same with US regulations
• Good practice: SW lifecycle processes
 –Overview of SW processes
 –Relationships between development, usability, risk management and maintenance
• 60601 with focus on chapter 14, contribution of SW to essential performance
 –Requirements of 60601 on software
 –Links between system level and software level
• 62304 - Software development lifecycle
 –Focus on SW development
 –Requirements analysis, architectural and detailed design, testing strategies
• Development For class C software
 –Specific testing strategies for class C SW

Day 2:
• Short intro to risk management - ISO 14971
 –The risk management process in general
• Software safety class
 –How to define / assess the software safety class
• Software risk in relation to 62304
 –Specific requirements for software risk management
• Concept cybersecurity
 –Introduction to cybersecurity and consequences for SW dev team
• Cybersecurity risk management process
 –Presentation of process and links with risk management process
 –Overview of requirements of UL 2900-1

Day 3:
• Agile SW development
 –Combining agile and regulations / standards
 –Exercise: defining an agile SDLC
• GDPR/HIPAA
 –What constitutes an electronic record and how to identify them
 –Requirements and impacts for SW design
• Tool validation
 –SW tool validation process: use a risk-based approach and how to adapt IQ OQ PQ to software.